

## ATTACHMENT A REMARKS

The telephone discussions with Examiner MacNeill are gratefully acknowledged. Applicant had requested an interview with the Examiner but, in the end, the Supervisory Primary Examiner decided that an interview "after FINAL" would not be appropriate, and it was recommended that a RCE be filed. Although it is believed that the claims presented are patentable for the reasons set forth below, an interview with the Examiner at the current stage of the prosecution is again respectfully requested.

Turning to the last Office Action, claims 1, 5, 7, 12-14 and 21 have been rejected under 35 U.S.C. § 102(b) as being "anticipated by" Silver. This rejection is respectfully traversed.

Silver discloses a breast pump in which the negative pressure is generated by a rigid piston arrangement wherein the piston can take the form of a rigid closed tube that is applied to the outside of the breast pump body (see Figs. 2 and 3). Silver also discloses a more conventional rigid plunger which moves inside the breast pump body (see Figs. 5 and 6). The Examiner appears to equate the gasket 41' shown in Figs. 5 and 6 with the flexible sleeve of claim 1. However, it is respectfully submitted that this is not correct. The gasket 41' serves only as a seal for a rigid piston and its movement does not create an increasing volume of reduced pressure. It is respectfully submitted that it does not make technical sense to equate this gasket/seal with a flexible sleeve, not least because only one end of the gasket/sleeve of Silver is fixed to anything (one end is fixed to the piston 36); while the other end is free to slide (and seal) the inside wall of the piston cavity as the piston moves up and down.

In short, Silver makes it quite clear that the gasket 41' is provided in the outside wall of a piston for the purposes of sealing against the interior side wall of the cylinder (see column 4, lines 53 to 55).

For the sake of completeness, it is noted that the piston itself is not a flexible sleeve either.

In summary, it is respectfully submitted that the rejection based on Silver is incorrect because the "flexible sleeve 41" referred to be the Examiner is in fact a

sealing gasket for a rigid piston and cannot therefore correspond to the flexible sleeve of Claim 1.

Claims 1, 5-14 and 21 have been rejected under 35 U.S.C. § 102(e) as being "anticipated by" the Britto reference. This rejection is respectfully traversed.

Britto discloses a manually operable breast pump having a flexible diaphragm 128 which is attached to a plunger 172 (see Fig. 1 and column 6, lines 15 to 18). In this regard, it appears that the Examiner probably meant to refer to a element 128 rather than element 140 in the arguments in Section 3 on page 2 of the Official Action.

Operation of a lever 216 causes the plunger 172 to displace the diaphragm 128 so as to create vacuum pressure in the suction chamber 12 under the diaphragm.

Britto suggests at column 12, line 62 that the diaphragm may be made of a thermoplastic elastomer. Figure 20 shows the diaphragm in an arrangement wherein the plunger has been lifted to its highest extent, i.e. the lever is depressed fully. This corresponds to the highest vacuum in the chamber below the diaphragm. In this position the diaphragm has a "fold" and the fold would inevitably be deformed (stretched) by the force of the vacuum acting directly on it. Thus, as soon as the diaphragm is deflected (moved) the pressure underneath it drops and the elastic diaphragm material will be deformed (stretched) by the pressure differential. Thus, as per column 6, lines 37 to 39 of Britto, the diaphragm material behaves as an elastomer and operation of the lever can cyclically "lift plunger 172 outward of suction bell 8, deflecting and deforming diaphragm 128 to expand pumping chamber 148, thus creating vacuum pressure within pumping chamber 148 and suction chamber 12". With respect to the arrangement of Fig. 20, "diaphragm 716 is deflected and deformed outward of chamber 720" (see column 6, lines 42 to 44).

The deformation or stretching of the diaphragm in Britto causes the user to expend extra energy by pumping. There is no disclosure whatsoever of a flexible sleeve wherein the configuration or material of the sleeve is such as to substantially prevent stretching of the sleeve on movement between a rest and displaced conditions, as required by Claim 1. The decreased pumping energy required is a key feature of the invention and the "non-stretchable" nature of the flexible sleeve which is the basis of

the feature clearly differentiates the invention as claimed in claim 1 from the conventional diaphragm disclosed by Britto.

For the sake of completeness, it is noted that while the invention is, of course, not limited to the specific embodiments disclosed in the application, the embodiment shown in Fig. 1 of the present application includes a flexible sleeve that has a concertina configuration that substantially prevents stretching of the sleeve (see page 11, lines 5 to 13). The embodiment shown in Fig. 4 represents an alternative solution, namely the use of a substantially non-stretch material. In this specific embodiment, the sleeve 12' comprises a layer of elastic material, for example silicone or a thermoplastic elastomer such as polyurethane, which is bonded, inlaid or insert moulded a substantially non-stretch layer such as a fabric mesh (see page 13, lines 18 to 23). The benefits of these "non-stretch" flexible sleeves are discussed on page 4, line 14 to page 6, line 3.

In summary with respect to the rejection based on Britto, it is respectfully submitted that the Examiner has overlooked the requirement of Claim 1 that the configuration of the sleeve or material of the sleeve is such as to substantially prevent stretching of the sleeve on movement between the rest and displaced conditions. In contrast, diaphragm 128 of Britto is inevitably stretched during operation because the vacuum generated by the movement of the plunger will "pull" the elastic diaphragm down.

Claims 15-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Britto and Silver as applied to claim 1 and further in view of Ytteborg. This rejection is respectfully traversed.

Although, again, the invention is not limited to this embodiment, in the embodiment shown in Fig. 6 of the present application, the provision of "soft material" in the horn allows a mother to manipulate her breast using her thumb together with her finger (see page 19, line 20 to page 20, line 2). This is possible because the horn includes "soft material" that comprises the thickness of the horn at a particular location. In contrast, the arrangement in Ytteborg comprises a two-part breast engaging horn in which the inner part 2 comprising the flexible membranes 14 is inserted inside an outer portion 1 comprising a rigid plastics material such that manipulation of the breast would

not be possible. In short, the flexible membranes of Ytteborg do not comprise the thickness of the horn.

It is respectfully submitted that the obviousness rejection based on Silver or Britto with Ytteborg with respect to the breast engaging portion (horn) is incorrect because, as discussed above, neither Silver nor Britto disclose the features alleged by the Examiner. Furthermore, the flexible membranes of the breast engaging portion of Ytteborg do not comprise at least one region of soft elastic material comprising the thickness of the horn at a particular region, as required by Claim 15. Thus, manipulation of the breast is not possible in Ytteborg.

Claims 2-4 have been rejected under 35 U.S.C. § 103(a) as being "unpatentable over" Silver or Britto in view of Kong. This rejection is respectfully traversed.

First, it is noted that only some of the disclosures in Kong are relevant to breast pumps. In particular, it is only the arrangements in Figures 1 to 4 and the corresponding discussion in the specification that can be of any relevance to the technical field of breast pumps. The other arrangements disclosed in Kong appear to be entirely inappropriate for use with breast pumps and thus are not relevant.

The Examiner alleges that the nursing pumps of Kong include a concertina-type diaphragm. However, even if it could be accepted (which it is not) that there is a disclosure in Kong of a concertina-type diaphragm in the context of a breast pump, it is clear that the breast pumps themselves are of a completely different configuration from those specified in claim 1.

In particular, claim 1 requires that the breast pump comprises (1) a body member including a breast engaging portion; and (2) a container attached to the body member. The container is used to collect the expressed milk. Located between the body member and the container is a valve means. The flexible sleeve of the present invention as claimed in claim 1 is located within the body member (see line 4 of claim 1). Thus, for example, the embodiment shown in Figure 1 of the present application shows a body member 2 separated from a container 32 by a one-way valve 28. The concertina sleeve 12 is located in the body member 2, i.e. "upstream" from the valve 28.

In contrast, in all of the nursing pumps disclosed in Kong, the flexible partition 26, 70 effectively constitutes the lower or bottom wall of a container for collecting the expressed milk. Thus, the flexible partition, even if it was to be equated with the flexible sleeve specified in claim 1, is not present in the body member of the breast pump, but instead is located in the container. Indeed, it is, in fact, part of the container.

Furthermore, it is not even clear that the nursing pump of Kong contains a valve as required by claim 1.

Further, while the Examiner refers to the flexible partitions of Kong as a "concertina shape sleeve", there is no such specific disclosure in Kong itself. Instead, there is only a mention that the excess partition could be gathered near one end of the body of the pump as illustrated in Fig. 1 (see paragraph [0034]).

In summary, the assertion that the claims are obvious in view of Silver or Britto in combination with Kong is incorrect because, as discussed above, neither Silver nor Britto disclose the features alleged by the Examiner. Further, the only arrangements disclosed in Kong which relate to a nursing pump are shown in Figures 1 to 4 and in each of these arrangements the flexible partition 26, 70 forms the lower wall of a container for holding the expressed milk. In contrast, claim 1 requires that a flexible sleeve is located within a body member that is separated from the container by a valve.

Thus, the arrangement in Kong is fundamentally different from that claimed and disclosed in Silver and Britto. The cited prior art references are, therefore incompatible because of the structural differences between the respective devices. Even a hypothetical combination would require wholesale changes to Silver or Britto so that the flexible partition formed part of the container for collecting milk, thereby taking it even further from claim 1.

Considering the latter point in more detail, even if a hypothetical combination of Kong with either of Britto or Silver were to be made, the skilled reader must re-engineer the breast pump of either Britto or Silver so that the pumps would have the arrangement shown in Figs. 1 to 4 of Kong, namely that the flexible partition would form part of the container for holding expressed milk. This would inevitably take the hypothetical combination outside the definition of claim 1. Further, there is no discussion whatsoever in Kong that the flexible partitions (whether or not they are concertina-

shaped) would in any way reduce the energy required to overcome the generated vacuum. Indeed, there is no recognition in Kong or any other of the cited references that stretching of a diaphragm is a problem. Indeed, Kong only proposes the flexible partition arrangement (with no mention of a concertina-shape) for the purpose of providing a variable volume chamber (see paragraph [0033]). Indeed, the only detail provided with respect to the flexible partition is that it is preferably a low-friction elastomeric material so as to create negative pressure within the fluid chamber 34 with as little friction and other opposing forces as possible (see final sentence of paragraph [0033]).

Claim 21 has been objected to "under 35 U.S.C. FR 1.75 as being a substantial duplicate of claim 1." In order to expedite the prosecution, claim 21 has been canceled.

Finally, new claims 22 and 23 have been added which are also believed to be clearly patentable over the prior art. Claim 21 is patentable for generally the same reasons as set forth above in support of the patentability of claim 2. Claim 23 is patentable for generally the same reasons as set forth above in support of the patentability of claim 5.

Allowance of the application in its present form is respectfully solicited.

**END REMARKS**